

K212077 Teleflex Rusch SoftSimplastic Foley CathetersJul 27, 2023
755 days to decisionK212077 · Product code: **EZL** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k212077/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Jul 2, 2021
Decision date	Jul 27, 2023
Days to decision	755 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Teleflexmedical, Inc.
Location	Jeffrey, NH, US
Contact	Kelley Breheim
510(k) history	64 submissions · 61 cleared · 1985-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212077/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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